PLEA: Nolo contendere.

DISPOSITION: 1–29–62. $1,800 fine, of which $1,200 was remitted.

6858. (F.D.C. No. 46381. S. Nos. 58–995 R, 59–003/4 R, 59–007/9 R, 59–012/3 R.)

INFORMATION FILED: 11–22–61, W. Dist. N.C., against **Carolina Cut-Rate Drug Store, Inc., Charlotte, N.C., Foster E. Thomas (vice president and registered pharmacist), and Rufus O. Harris (pharmacist employee).**

CHARGE: Between 3–23–61 and 5–4–61, *Equanil tablets* and *Pentids tablets* were each dispensed 4 times.

PLEA: Guilty.

DISPOSITION: 4–5–62. $750 fine against the defendants jointly.

6859. (F.D.C. No. 46731. S. Nos. 25–166/70 R, 85–787 R.)

INFORMATION FILED: 4–20–62, W. Dist. Mo., against **Gerald R. Fredman, t/a Fredman's Drugs, Kansas City, Mo., and Sanford Lerenberg (assistant manager).**

CHARGE: Between 6–10–60 and 7–8–60, *meprobamate tablets* were dispensed 3 times and *Seconal Sodium capsules* were dispensed twice upon request for a prescription refill without obtaining authorization from the prescriber, and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty by Fredman to all counts; by Lerenberg to 2 counts.

DISPOSITION: 4–27–62. Fredman—$500 fine; Lerenberg—$200 fine.

6860. (F.D.C. No. 45986. S. Nos. 18–693 R, 18–695 R.)

INFORMATION FILED: 8–2–61, Dist. Utah, against **John R. Berntsen, t/a John R. Berntsen Pharmacy, and W. Hugh Leonard (pharmacist), Provo, Utah.**

CHARGE: Between 10–3–60 and 10–10–60, *Thorazine tablets* were dispensed twice upon requests for prescription refills without authorization from the prescriber.

PLEA: Berntsen—guilty to 2 counts; Leonard—guilty to one count.

DISPOSITION: 10–23–61. Berntsen—$400 fine; Leonard—$100 fine.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6861-6900

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and including, in one case, the entry of a decree of injunction; and (2) a criminal proceeding which was terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceeding was against the *firm* charged to be responsible for the violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *January 7, 1963.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 6874, 6895; an imitation of, and sale under name of, another drug, No. 6875; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6863, 6894; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6863, 6874, 6894.

668105—63——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6861–6900

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in whole or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article was for use by man and contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulations designated as, habit forming, and its label failed to bear the statement "Warning—May be habit forming."; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6861. Entoquel syrup and Entoquel with Neomycin syrup. (F.D.C. No. 46218. S. Nos. 20-908/9 R.)

QUANTITY: 25 6-oz. btls. of *Entoquel syrup* and 32 6-oz. btls. of *Entoquel with Neomycin syrup*, at Cleveland, Ohio, in possession of Grey Drug Stores, Inc.

SHIPPED: 2–6–61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: (Btl.) "Entoquel Syrup (Thihexinol Methyl Bromide) Caution: * * * White Laboratories, Inc., Kenilworth, New Jersey. Dosage * * * Each Teaspoon (5 cc) contains * * * Thihexinol Methyl Bromide–5 mg. Alcohol –1%" and "Entoquel with Neomycin Syrup Caution: * * * White Laboratories, Inc. * * * Dosage: * * * Each teaspoon (5 cc) contains * * * Thihexinol (Entoquel)–5 mg. Neomycin (from the sulfate)–50 mg. Alcohol–0.5%."